UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 23-8008

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
The Honorable Robert B. Kugler, No. 19-2875

MEDICAL MONITORING CLASS PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' PETITIONS FOR PERMISSION TO APPEAL PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 23(f)

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Plaintiff-Respondents ("Plaintiffs") submit this response on behalf of the medical monitoring class plaintiffs ("MM Plaintiffs").[1] The MM Plaintiffs also adopt and incorporate the Economic Loss Plaintiffs' separately submitted response ("EL Br.").

I. INTRODUCTION

This MDL involves one of the largest FDA recalls in history due to Defendants' manufacture and sale of dangerously adulterated valsartan-containing drugs (VCDs) and flagrant violations of current Good Manufacturing Practices (cGMPs). The VCDs, which were widely prescribed for hypertension, contained genotoxic carcinogens called NDMA and NDEA. ZHP, the largest manufacturer of contaminated valsartan by market share, admitted that the contamination created an "unacceptable carcinogenic risk" that required recall. *See* D.E. 2057-10. MM Plaintiffs seek medical monitoring because they now face increased risk of developing certain cancers due to ingesting Defendants' contaminated VCDs.

[1] Defendants-Respondents ("Defendants") filed four petitions for leave to appeal the District Court's Class Certification Order ("Order"), 1:19-md-02875, D.E. 2261 (D.N.J. Feb. 8, 2023). The two petitions that focus on medical monitoring are the ZHP manufacturers' petition ("ZHP Br."), and the petition filed by manufacturers Mylan and Aurobindo, styled as the "NDEA Defendants" Brief ("NDEA Br."). *See In re: Valsartan Losartan & Irbesartan Prods.*, No. 23-8008 (2023).

Class members will only be entitled to this remedy if there are findings on the merits of common misconduct, the dangers of the nitrosamines, and the feasibility of a monitoring program.

The MDL Court correctly determined that claims involving Defendants' uniform conduct towards class members resulted in each class member's unwitting ingestion of pills containing genotoxic substances considered probable human carcinogens. The Court was "well-positioned to decide which facts and legal arguments [were] most important," and diligently exercised its discretion under Rule 23 and rendered a mixed ruling by granting certification of two classes and denying certification of another. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 310 (3d Cir. 2008) ("*Hydrogen Peroxide*") (trial courts have "broad discretion to control proceedings and frame issues for consideration under Rule 23").

Defendants selectively challenge aspects of the Court's ruling that were adverse to them, but they do not and cannot show that interlocutory appellate review is warranted. *First*, Defendants' argument that medical monitoring is *per se* unsuitable for class treatment is unsupported by the law of this Circuit or any other. *Second*, the MDL Court considered the purported factual and legal variations that Defendants identify, but properly held that they presented common

issues for trial, if they were relevant at all. *Third*, Defendants' manageability arguments are premised on a misstatement of the appropriate inquiry and otherwise unfounded given the Court's careful exercise of discretion in addressing different aspects of the certified classes. *Fourth*, the MDL Court's Order complies with *Daubert* and does not reflect any error.

II. RELEVANT BACKGROUND

On November 10, 2021, the MM Plaintiffs moved for class certification. MM Plaintiffs sought a multistate MM Independent Claim Class under Rule 23(b)(3) or (b)(2) (for class members residing in states where medical monitoring is an independent claim) and a multistate MM Remedy Class under Rule 23(b)(2) (for class members residing in states where medical monitoring is a remedy).

The MDL Court denied certification of the Rule 23(b)(2) Independent Claim (b)(2) class and granted certification of the other two classes.[2] For both classes, the MM Plaintiffs proposed, and the Court adopted, a conservative and objective class definition: only people who, *solely by virtue of taking their VCDs*, consumed at least the Lifetime Cumulative Threshold ("LCT")[3] of NDMA, NDEA,

[2] One class is divided into two subclasses to accommodate different states' injury requirements.

[3] LCT calculations, among other places, are in Table 5 of the Class Certification Order.

or both, were included. The LCT calculation also took into account both differences in VCD daily dosage size and differing levels of NDMA/NDEA contamination among Defendants' products. Thus, the fact that consumers unsurprisingly ingested different dosages is addressed in the class definition. Order at 49-50.

The LCT arose out of the expert reports of Drs. Madigan and Panigrahy, who reviewed numerous studies analyzing lifetime cumulative exposure levels associated with a statistically significant likelihood of developing various cancers. The MDL Court addressed the admissibility of these general causation opinions in response to *Daubert* motions prior to its certification order.[4] MM Plaintiffs' expert Dr. Kaplan also created a common medical monitoring program that outlined a discrete list of cancers and the accompanying testing and screening he recommends for these cancers due to the enhanced risk created by Defendants' products. *See* D.E. 2024-3 at 2-4.

In certifying the MM classes, the Court considered the extensive factual record showing Defendants' common misconduct, the MM Plaintiffs' trial plan,

[4] *See*, *e.g.,* Evid. Hr'g, D.E. 1959 at 65:14-17 (detailing Dr. Panigrahy's opinion that the amounts of NDMA in the contaminated tablets were on average around 187 to 200-fold increase over the FDA levels).

the MM class certification experts' opinions, and carefully analyzed the robust body of law regarding certification of medical monitoring.

III. STANDARD OF REVIEW[5]

This case highlights why "[i]nterlocutory appeals are generally disfavored" as "undermin[ing] 'efficient judicial administration' and encroach[ing] upon the prerogatives of district court judges, who play a 'special role' in managing ongoing litigation.'" *Ruffin v. Avis Budget Car Rental, LLC*, No. 11-01069, 2014 WL 4610421, at *1 (D.N.J. Sept. 15, 2014) (quoting *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 106 (2009)).

IV. ARGUMENT

A. Defendants' False Contention that Medical Monitoring is *Per Se* Unsuitable for Class Treatment is Not a Valid Rule 23(f) Argument.

Defendants' threshold argument is that medical monitoring classes are categorically unsuitable for class treatment. This extreme position removes their arguments from the specifics of this Court's ruling and crosses the line into a form of policy advocacy that is untethered to Rule 23 or the facts of this case.

Medical monitoring is a well-established claim and remedy. Medical monitoring classes continue to be certified *all across the country* in both state and

[5] The MM Plaintiffs incorporate the standard of review in the EL Brief.

federal courts. And, this Court recently addressed medical monitoring classes, so review would neither facilitate development of the law on class certification nor implicate novel or unsettled questions of law. *See In re Nat'l Football League Players Concussion Inj. Litig.*, 821 F.3d 410 (3d Cir. 2016).

Common facts regarding misconduct, involuntary ingestion, the existence and cause of contamination, as well as the discrete and focused time period, places this case squarely within a line of authority where entitlement to monitoring rises or falls on common questions.[6] Dr. Kaplan proposes a common program suitable for everyone who meets the specific class membership requirements; Defendants' expert asserts that no one should be monitored. This stark, categorical disagreement articulates a clear issue for common class resolution at trial. *See* Pl's Reply Mem. ISO Class Certification, D.E. 2059 at 10-13; *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 457 (2016) ("When, as here, the concern about the

[6] *See, e.g.*, *id.; In re Diet Drugs Prod. Liab. Litig.*, No. 98-20626, 1999 WL 673066, at *1 (E.D. Pa. Aug. 26, 1999); *see also Sullivan v. Saint-Gobain Performance Plastics Corp.*, No. 5:16-cv-125, 2019 WL 8272995, at *3, *18 (D. Vt. Aug. 23, 2019); *In re Nat'l Collegiate Athletic Ass'n Student-Athlete Concussion Inj. Litig.*, 314 F.R.D. 580, 584 (N.D. Ill. 2016); *In re Deepwater Horizon*, 295 F.R.D. 112, 161 (E.D. La. 2013); *Donovan v. Philip Morris USA, Inc.*, 268 F.R.D. 1, 5, 8 (D. Mass. 2010); *Perrine v. E.I. du Pont de Nemours & Co.*, 694 S.E.2d 815, 896 (2010); *In re Telectronics Pacing Sys., Inc.*, 172 F.R.D. 271, 278 (S.D. Ohio 1997).

proposed class is not that it exhibits some fatal dissimilarity but, rather, a fatal similarity—[an alleged] failure of proof . . . —courts should engage that question as a matter of summary judgment, not class certification."). It is not a basis for 23(f) review.

Defendants primarily rely upon (and misstate) two cases they cited 24 times in their certification briefing: *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 265 (3d Cir. 2011) ("*Gates*") and *Barnes v. Am. Tobacco Co.*, 161 F.3d 127 (3d Cir. 1998) ("*Barnes*"). *See generally*, D.E. 2012. They ignore that this Court much more recently *affirmed certification* of a medical monitoring class in *In re Nat'l Football League Players Concussion Inj. Litig.*, where the facts were less straightforward than here. 821 F.3d at 423, 434 (individual differences in head trauma were outweighed by common questions regarding the NFL's knowledge and conduct and "common scientific questions regarding causation").

Gates involved an attenuated theory of environmental exposure resulting from industrial wastewater dumped into an aquifer decades earlier. 655 F.3d at 269. The *Gates* plaintiffs proposed an expansive class definition that included every resident of a town located near the waste site over a period of 34 years. *Id*. at 259. Further, although the *Gates* plaintiffs sought to prove that the residents of the town were exposed via ingestion of contaminated groundwater, they found no

evidence of contamination in the town's water supply. *Id*. Thus, the sole theory of exposure plaintiffs proposed at class certification was tenuous: that the wastewater dumped in the aquifer "evaporated into the air from the shallow aquifer and was swept by the wind over" the nearby town where it was inhaled by the town's residents. *Id*. at 258. It is completely inapposite.[7]

In *Barnes*, plaintiffs filed suit against major tobacco companies seeking medical monitoring for those who began smoking before age 19. 161 F.3d at 132. The class definition lacked any objective measure of exposure other than age of smoking initiation. *See id*. Rather, plaintiffs had to prove that defendants' manipulation of nicotine content in cigarettes caused each class member's addiction and thereby "rendered their choice to smoke nonvoluntary." *Id*. at 144-45. The *Barnes* court held that the class could not be certified because "nicotine addiction must be determined on an individual basis" and would have required cross-examination of each class member regarding their "individual smoking history." *Id*. at 145-46.

[7] Defendants misleadingly quote *Gates* for the proposition that medical monitoring classes "generally" founder for lack of cohesion, when the opinion actually states that classes "***may*** founder." 655 F.3d at 264 (emphasis added).

Gates and *Barnes* do not preclude certification; rather they are two cases where medical monitoring was not appropriate due to overbroad class definitions and attenuated (and in some cases arguably voluntary/self-administered) nature of the exposure. By contrast, here, Defendants caused MM Plaintiffs' direct harm via involuntary ingestion of NDMA/NDEA-contaminated valsartan. Indeed, MM Plaintiffs have access to pharmacy and testing records that detail dosages and contaminant levels. They have carried their burden of establishing a common question for the class through expert testimony that "presented [a] way to measure the actual minimum levels of exposure of individual class members." *Gates*, 655 F.3d at 267.

B. The MDL Court Appropriately Addressed Purported Factual Variation.

Defendants cannot and do not make specific arguments about the Rule 23(a) elements or attempt to show that individual fact issues outweigh common issues. Instead, Defendants list purportedly individual fact defenses and expect the purported complexity to speak for itself. But the "[d]ecision on class certification may implicate 'highly fact-based, complex, and difficult matters.'" *Hydrogen Peroxide*, 552 F.3d at 310. Complexity alone does not defeat certification.

1. The conservative class definition renders irrelevant most or all of the issues raised by Defendants.

Defendants quote *Gates* to assert that the MDL Court clearly erred by overlooking personal characteristics, including "the age of the class member being exposed, the length of exposure, [and] other individual factors such as medical history." *See* ZHP Br. at 7; NDEA Br. at 11 (quoting *Gates*, 655 F.3d at 268). Defendants excise the most pertinent part of the quotation, which provides that Plaintiffs can account for these differences by "showing the exposure was so toxic that *such individual factors are irrelevant*." *Gates*, 655 F.3d at 268 (emphasis added). This is precisely what Plaintiffs did by setting the LCT at a conservatively high level, which the MDL Court found "both indicates and confirms heightened nitrosamine exposure" and "necessarily appl[ies] to all MedMon class members," regardless of individual characteristics. Order at 64.

Relatedly, Defendants argue that the MDL Court failed to consider that exposure to nitrosamine or other carcinogens may occur in daily life. Defendants are incorrect that environmental exposure to other carcinogens is a superseding cause; this is nothing more than a common question among class members. In considering these arguments at length, the MDL Court observed that "[t]he irony in defendants' argument is that it points in a general way to what the scientific

community for the last 30 years has published about nitrosamine exposure: that a probable increase in cancer development is attributable to an increase in exposure to nitrosamines—via VCD ingestion, inhalation, etc." *Id*. at 65. The MDL Court correctly observes that Plaintiffs defined the LCT conservatively to ensure that the exposure to NDMA/NDEA caused by Defendants' products caused *significantly increased risk* of developing cancer, regardless of other natural exposure. *Id*. at 67 ("[t]he higher the LCT number, the more likely the LCT itself has an increased statistical probability of accuracy, and therefore identifies with greater probability an individual with an increased cancer risk and who thus belongs in" the MM Class).

2. <u>Variation in contamination between batches is a speculative defense.</u>

Defendants argue that the MDL Court failed to consider variation in contamination between batches of valsartan, yet it is incontrovertible that Defendants placed contaminated VCDs in the drug supply chain and sold them to the MM Plaintiffs. This "grounds all of plaintiffs' claims" and presents a common set of facts that are "capable of proof at trial through evidence that is common to the class rather than [is] individual to its members.'" Order at 21 (citation omitted). As stated by the Court, at best, Defendants' variation argument "in effect poses a

legal causation issue common to the entire class," which proves (and does not disprove) predominance. *Id*. at 65.

The MDL Court also considered, but excluded Defendants' expert testimony on intra-batch variation due to their expert's use of "deficient scientific methodology." *Id*. at 76-77. Specifically, the Court held that the expert's methodology was faulty because it was based on a single Aurobindo internal study and "did not include a comparison of Aurobindo's initial test results either with Aurobindo's second results or with the FDA subsequent test results." *Id*. at 77.

It was not error for the MDL Court to hold that Defendants' speculative common defense did not preclude certification. *Cf. Beck v. Maximus, Inc.*, 457 F.3d 291, 301 (3d Cir. 2006) (class representative could not be disqualified on adequacy ground based on "a speculative defense"); *In re Suboxone Antitrust Litig.*, 967 F.3d 264, 273 (3d Cir. 2020). Overall, Defendants' arguments merely underscore the MDL Court's careful consideration and the absence of error; in no way does it present appropriate issues for interlocutory review.

C. The MDL Court Appropriately Addressed Purported Legal Variations.

Defendants argue that the MDL Court ignored variations in state law, notwithstanding the MDL Court's nearly 400 pages of combined opinion and

accompanying appendices, which demonstrates painstaking review of each state's laws under this Circuit's well-established precedent and creation of classes and subclasses to align them.

Tellingly, Defendants rely on factually inapposite, out-of-circuit decisions.[8] But, this Court, which has had frequent occasion to examine multistate classes (another reason interlocutory appeal is not appropriate) has never required identical law to create multistate classes. *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 301 (3d Cir. 2011) (en banc) ("As long as a sufficient constellation of common issues binds class members together, variations in the sources and application of applicable laws will not foreclose class certification." (cleaned up)). Under the Third Circuit's analytical framework, trial courts must ask whether the state law groupings are: (1) based on "predictable patterns" within a "broad constellation" of

[8] *In re St. Jude Med., Inc.*, 425 F.3d 1116, 1122 (8th Cir. 2005) (holding that monitoring would be duplicative for class of mechanical heart valve recipients); *In re NHL Players' Concussion Injury Litig.*, 327 F.R.D. 245, 260, 266 (D. Minn. 2018) (plaintiffs failed to create subclasses that could account for differences in state laws, unlike those in the present case); *Elson v. Black*, 56 F.4th 1002, 1007-08 (5th Cir. 2023) (denying certification in an opinion turning on Fifth Circuit caselaw, where the plaintiffs failed to adequately brief the laws of each state); *In re Nat'l Prescription Opiate Litig.*, 976 F.3d 664, 667 (6th Cir. 2020) (discussing the creation of a "negotiation" class, consisting of "all cities and counties throughout the United States" and created with the explicit intent to foster settlement rather than advance the litigation).

laws; (2) present "insuperable" obstacles that render the litigation unmanageable; and (3) present a "workable solution." *Grandalski v. Quest Diagnostics, Inc.*, 767 F.3d 175, 183-84 (3d Cir. 2014).[9] Here, the Court has asked, and answered, each question.

This case is on all fours with *In re Prudential*, 148 F.3d 283, 315 (3d Cir. 1998), where the proposed groupings consisted of a "series of charts setting forth comprehensive analyses of the various states' laws potentially applicable to their common law claims." *Id.*; *see also Grandalski*, 767 F.3d at 183 (*Prudential*'s "in-depth treatment justified the MDL Court's decision to group state laws in that case"). The MDL Court did not endorse either sides' interpretation as a matter of course either. It independently reviewed each state's law and subsequently found that there were no insuperable obstacles to class treatment, in a manner that comports with the Court's instructions in *Grandalski*, *In re Warfarin*, and *In re*

[9] Like other courts in this Circuit, the MDL Court applied the majority approach where no precedent existed, which permits medical monitoring as either a remedy or independent claim as described in the Order at 336-89. *See, e.g.*, *Ryu v. Bank of Hope,* No. 19-18998, 2021 WL 50255, at *4 n.5 (D.N.J. Jan. 6, 2021) ("Federal courts . . . usually presume that a state court will follow the majority view on an undecided issue."); *Small v. United States*, 333 F.2d 702, 704 (3d Cir. 1964) ("We therefore assume that the courts of Delaware would follow the majority view"); *Durr Mech. Constr., Inc. v. PSEG Fossil, LLC*, 516 F. Supp. 3d 407, 415 (D.N.J. 2021) ("Lacking more specific guidance, a federal court may identify a majority view and predict that a state supreme court would adopt it.").

Prudential. These immaterial "nuances" in state law do not defeat legal predominance. *Id.*; *In re Sch. Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir. 1986) (plaintiffs made "creditable showing" that state law groupings did not present "insuperable obstacles" to trial management and "variations in the rights and remedies available to injured class members under the various laws of the fifty states [did] not defeat commonality and predominance"); *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516 (3d Cir. 2004).

The purported issues Defendants raise—all of which the MDL Court considered in the detailed certification and earlier rulings—reflect a misstatement or misunderstanding of the law. For example, Defendants cite *Sinclair v. Merck & Co*. to argue that, in some states, "monitoring is limited to toxic tort cases." However, *Sinclair* did not hold this; it instead stands for the proposition that there is an injury requirement for medical monitoring under the state products liability statute. 948 A.2d 587, 591, 594-95 (N.J. 2008); ZHP Br. at 11.

Defendants also identify (without analysis) several purported requirements under state law that have no bearing on this case. Some states require disease detection procedures; here, well-established methods of cancer screening exist and are identified in Plaintiffs' screening program. Order at 60; D.E. 2024-4 at 91:6-94:1 (describing how each linked cancer would be screened under his proposed

protocol). The same is true of any state law requirement that treatment for the disease exists. Cancer treatment undeniably exists and "[i]dentifying a malignant cancer early in its development, . . . is vital to ensure that the subject receives treatment in a timely fashion, therefore affording a better chance of control and cure." D.E. 2024-3 at 4. Indeed, certain tests, such as colonoscopies, can be cancer treatments. *See e.g.*, D.E. 2024-4 at 80:18-22. Finally, Defendants raise whether subcellular injury suffices to show injury in certain states; the MDL Court expressly incorporated this consideration in the subclass structure.

D. The MDL Court Appropriately Addressed Dueling Expert Opinions.

Defendants again (as they did in briefing before the MDL Court) challenge Plaintiffs' expert Dr. Kaplan, a practicing oncologist, who devised the medical monitoring plan. In essence, Defendants argue that the MDL Court erred because it did not accept the opinion of Defendants' expert that no monitoring is necessary as fact. Yet Defendants do not and cannot explain why the Court's rulings were error, let alone clear error. As the MDL Court aptly observed, at class certification, the elements of medical monitoring need not be "proven," rather they "serve as a useful heuristic to bear out that common legal issues and facts of an independent medical monitoring claim predominate across the class." Order at 64;

In re Suboxone Antitrust Litig., 421 F. Supp. 3d 12, 26 n.2 (E.D. Pa. 2019) ("a plaintiff has no obligation to establish the merits of the case at the certification stage").

First, Defendants improperly conflate Dr. Kaplan's testimony that *treatment* for cancer depends on "the patient's specific situation" with a non-existent admission that no *screening* program can be applied to the class generally (when clearly Dr. Kaplan opined to the contrary). ZHP Br. at 8-9; NDEA Br. at 10. Defendants elide the distinction between screening (which is categorical) and treatment itself. D.E. 2059 at 10-11. The MDL Court properly disregarded this apples-to-oranges comparison.

Second, Defendants fault the MDL Court for declining to credit their own expert's opinion—that the risks of any medical monitoring outweigh the benefits—over Dr. Kaplan's opinion to the contrary. While a trial court "may not decline to resolve a genuine legal or factual dispute because of concern for an overlap with the merits," it may, "[i]n its sound discretion . . . find it unnecessary to consider certain expert opinion with respect to a certification requirement." *Hydrogen Peroxide*, 552 F.3d at 324.

The MDL Court considered the supposed risks of screening that Defendants' expert identified, but declined to hold that these risks precluded certification

because they were "in effect questioning the need for a medical monitoring program and thereby raising an implied opinion about the increased risk of cancer development." Order at 65. It was a proper use of the MDL Court's discretion to conclude that these risks did not preclude class certification, but rather created a common question of fact as to medical necessity that "need not be resolved at this stage." *Id*. at 64-65.

Third, Defendants' comparison of the medical monitoring program in this case to the program in *Gates* is unavailing because plaintiffs' expert in that case failed to consider the "effectiveness or potential risk" of their proposed program of "serial MRIs and neurological examination." 655 F.3d at 269. By contrast, Dr. Kaplan has devised an "enhanced medical monitoring program" based on the risk of cancer caused by ingestion of contaminated VCDs and based on procedures he would consider medically necessary in light of his decades of experience with cancer screening. Order at 94-95.

E. Defendants' Arguments About Manageability Are Wrong.

Defendants misstate the manageability inquiry and inaccurately speculate about what the class trial(s) would look like.

1. Defendants fundamentally misrepresent the case and the MDL Court's approach going forward.

The Court has certified two MM classes, one of which contains two subclasses. *See* Order at 6 & Table 7. Manageability is but one of "several non-exclusive factors to consider" in assessing the superiority requirement under Rule 23(b)(3). *Kantor v. Hiko Energy, LLC*, 100 F. Supp. 3d 421, 431 (E.D. Pa. 2015). This analysis requires a comparative approach, in which a court must "balance, in terms of fairness and efficiency, the merits of a class action against those of 'alternative available methods' of adjudication.'" *In re Prudential*, 148 F.3d at 316 (citation omitted). It defies reason that thousands or millions of trials are more manageable than how the MDL Court would handle the adjudication of common facts that do not differ by class member to class member.

Following class certification, the MDL Court presumably will try (or prepare for trial and remand) a series of subclasses and claims, organized by plaintiff type and defendant groups (initially, each API manufacturer and finished-dosed manufacturer incorporating that API). In doing so, the MDL Court will utilize its discretion and apply its intimate familiarity with the claims and facts in this case garnered through years of careful oversight.

2. Defendants' manageability argument runs counter to Third Circuit precedent.

Manufacturing Defendants rely on inapposite cases to essentially argue that neither nationwide nor multistate class actions are ever appropriate, again taking the argument out of Rule 23(f) analysis and into a broadside against class trials.[10]

This Court has observed that "[m]anageability is a practical problem, one with which a district court generally has a greater degree of expertise and familiarity than does the appellate court." *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 191 (3d Cir. 2001) (citation omitted). This observation is particularly apt in MDL proceedings, where judges have "broad discretion to determine the course and scope of pretrial proceedings" in managing complex coordinated proceedings. *In re Light Cigarettes Mktg. & Sales Pracs. Litig.*, 856 F. Supp. 2d 1330, 1332 n.2 (J.P.M.L. 2012). "The [MDL] Court's evaluation must be 'granted a wide range of discretion.'" *Newton,* 259 F.3d at 191 (quoting in part *Link v. Mercedes Benz of N. Am., Inc.*, 550 F.2d 860, 864 (3d Cir. 1977)).

[10] For instance, Defendants rely upon *In re Am. Med. Sys., Inc.*, 75 F.3d 1069 (6th Cir. 1996), which other courts observed "ignore[d] the essence of Rule 23 because of [a] philosophical disagreement with the effects of Rule 23." *Cook v. Rockwell Int'l Corp.*, 181 F.R.D. 473, 477 (D. Colo. 1998) (quoting in part *Telectronics,* 172 F.R.D. at 276).

Moreover, Defendants prematurely ask this Court to rule on a trial management plan that has not yet been set. *In re Cmty. Bank of N. Va. Mortg. Lending Pracs. Litig.*, 795 F.3d 380, 410 (3d Cir. 2015) (stating that the district court need not "settle on any particular solution at the same time that it certifie[s] the class," and refusing to do so does not mean "the litigation [will be] unmanageable").

F. Defendants' Other Arguments Fail to Show Error.

1. The MDL Court's *Daubert* rulings on general causation experts are not immediately appealable.

Defendants question the merits of the MDL Court's prior *Daubert* rulings on general causation experts. Yet *Daubert* rulings are not an "order granting or denying class-action certification" and "the Advisory Committee notes explicitly describe Rule 23(f) as not extending to any other type of order, even where that order has some impact on another portion of Rule 23." *McKowan Lowe & Co. v. Jasmine, Ltd.*, 295 F.3d 380, 389–90 (3d Cir. 2002) (citing cases and agreeing with "other circuits [who] have also been scrupulous about limiting Rule 23(f) inquiries to class certification issues"); *see also* EL Br. at 16-17 (discussing the same).

Thus, the MDL Court's decisions on general causation experts are not at issue on class certification. *See Williams v. Jani-King of Phila. Inc.*, 837 F.3d 314, 322 (3d Cir. 2016) (appeal of class certification decision "is not the proper place

for us to answer [a merits] question"). Rule 23(f) is a narrow exception to the final judgment rule and does not confer appellate jurisdiction over every order that preceded the MDL Court's class certification order. *See Reinig v. RBS Citizens, N.A.*, 912 F.3d 115, 132–33 (3d Cir. 2018) ("a mere nexus between [] two orders is not sufficient to justify a decision to assume jurisdiction" under Rule 23(f)).

2. The MDL Court did not err by declining to consider an unrelated *Daubert* opinion from *In re Zantac*.

Defendants argue that the MDL Court erred because it should have considered an order excluding testimony by plaintiffs' general causation experts in *In re Zantac (Radnitidine) Prods. Liab. Litig.*, No. 20-MD-2924 (S.D. Fla. Dec. 6, 2022) (cited in ZHP Br. at 8 & n.1; NDEA Br. at 3-4 & n.1). As described in the EL Brief, Defendants' comparison is inapt for various reasons, including that here, NDMA/NDEA contamination was *present at the time of manufacture*, and the MDL Court structured classes based on the LCT, "a feasible mechanism for identifying members in a statistically appropriate and sufficiently accurate manner." Order at 69; EL Br. at 17 n.9.[11]

[11] Defendants imply that the District Court did not give appropriate attention to the *Daubert* rulings because the resulting order was shorter than in another case. Comparing page counts is not a valid argument.

3. The NDEA Defendants' Specific Arguments Do Not Show Error.

The NDEA Defendants assert in passing that the certification order places settlement pressure, but they do not back up the argument, and MM Plaintiffs refer to the EL Brief in response.

The NDEA Defendants' other arguments boil down to an argument that, on the merits, their conduct was not as harmful as the conduct of the other Defendants because the NDEA in their recalled products was not as potent as the NDMA in other defendants' recalled products. This has nothing to do with Rule 23 or the MDL Court's identification of common issues.

The NDEA Defendants also ignore that the MDL Court accounted for any differences between NDEA and NDMA in the class definition, insofar as a class membership requires much more consumption of products manufactured by the NDEA Defendants. Order at 50.

Finally, the NDEA Defendants' invitation for this Court to revisit *Daubert* rulings related to general causation—i.e., the question of the specific cancers to which NDEA is linked—is improper. The NDEA Defendants do not and cannot dispute *in this context* the findings that the products are linked to pancreatic cancer (they concede this in their brief), or that Plaintiffs have presented evidence that it is

linked to other cancers and this is under consideration by the Court.[12] These are not individual issues, and are not part of Rule 23(f) analysis. Even if the class definition (which, again, factors in whether the Valsartan contained NDMA or NDEA) could be called a factual finding, the MDL Court's factual finding was not clearly erroneous because it was not "completely devoid of minimum evidentiary support displaying some hue of credibility." *Giles v. Kearney*, 571 F.3d 318, 322 (3d Cir. 2009) (citation omitted).

V. CONCLUSION

For the above reasons, Rule 23(f) review is not warranted.

[12] Defendants overlook testimony by Dr. Lagana and Dr. Hecht, who "have not been limited on NDEA." D.E. 2059 at 3; D.E. 1958 at 2 (declining to limit either expert). Both provided testimony that NDEA could cause other cancers. D.E. 1793 at 18 n.14, 27-28. Plaintiffs will also be moving for clarification that Dr. Panigrahy's NDEA opinions were not excluded. The MDL Court is addressing these issues in further proceedings. D.E. 2074 at 10.

Dated: March 23, 2023

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LOCAL APPELLATE RULE 46.1 CERTIFICATION

I hereby certify, pursuant to L.A.R. 46.1, that I am a member in good standing of the Bar of the United States Court of Appeals for the Third Circuit.

Dated: March 23, 2023

/s/ Nicholas Migliaccio
Nicholas Migliaccio

CERTIFICATE OF COMPLIANCE, IDENTICAL COPIES, AND VIRUS SCAN

I hereby certify that:

1. This response complies with the type-volume limitation of Fed. R. App. P. 5(c) because it contains 5,162 words, as determined by Microsoft Word, the word processing software used to prepare this petition.

2. This response also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman size 14 font.

3. The text of the electronic version of this response filed via CM/ECF is identical to the text of the paper copies, if any, filed with the Court.

4. The electronic version of this petition was virus checked using Microsoft Defender 1.385.930.0 and no virus was detected.

Dated: March 23, 2023

/s/ Nicholas Migliaccio
Nicholas Migliaccio

CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2023, I electronically filed the foregoing with the Clerk of the United States Court of Appeals for the Third Circuit through the CM/ECF system. A true and correct copy was sent via electronic mail per agreement of the underlying parties to all counsel of record.

Dated: March 23, 2023

/s/ Nicholas Migliaccio
Nicholas Migliaccio